

PATENT COOPERATION TREATY

PCT

REC'D 14 MAR 2005

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT

(PCT Article 36 and Rule 70)

| | | |
|--|--|--|
| Applicant's or agent's file reference PP19766.002 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US03/29167 | International filing date (day/month/year) 15 September 2003 (15.09.2003) | Priority date (day/month/year) 15 September 2002 (15.09.2002) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/385, 39/02, 39/09, 39/00 and US Cl.: 424/197.11, 234.1, 244.1, 184.1, 236.1, 831 | | |
| Applicant CHIRON CORPORATION | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ____ sheets.</p> | | |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | |
| Date of submission of the demand 12 April 2004 (12.04.2004) | Date of completion of this report 05 March 2005 (05.03.2005) | |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230 | Authorized Officer S. Devi, P.E.D. Telephone No. (570)272-1600 | |

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/29167

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-31 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the claims:
pages 32-34 as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the drawings:
pages NONE as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/29167**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>NONE</u> | YES |
| | Claims <u>1-17</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-17</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-17</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-17 lack an inventive step under PCT Article 33(3) as being obvious over CHIRON S.P.A. in view of Michon *et al.*

CHIRON S.P.A. disclosed immunogenic compositions or vaccines comprising two or more of GBS1 through GBS689 proteins or polypeptides, including GBS80 and GBS691 proteins or polypeptides, or fragments thereof, and a streptococcal saccharide antigen. A method of making the compositions or vaccines and a method of treating an animal using the compositions or vaccines are taught. The saccharide antigen is linked to a carrier protein, such as, tetanus toxoid, diphtheria toxoid, or CRM197.

CHIRON S.P.A. does not expressly teach the streptococcal saccharide antigen in the vaccine to be of GBS serotype Ia, Ib, or III.

However, Michon *et al.* taught the use of GBS type II or III saccharide antigen covalently coupled to a bacterial carrier protein, such as, CRM197 or tetanus toxoid, in conjugate vaccines and multivalent vaccines.

The instant claims lack an inventive step because it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the streptococcal saccharide antigen conjugate in CHIRON S.P.A.'s immunogenic composition or vaccine with Michon's

GBS type II or III saccharide antigen conjugate to produce the instant invention with a reasonable expectation of success. Given Michon's teaching that such saccharide antigen conjugates are usable in multivalent vaccines, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of producing a multivalent vaccine, which would advantageously provide GBS saccharide- and GBS protein- or polypeptide-specific immunity against multiple GBS serotypes.

----- NEW CITATIONS -----